

### **Remarks**

Claims 19, 23 and 127-132 are pending in this application. Pursuant to a restriction requirement, claims 1-8 and 29-126 are canceled without prejudice to Applicants' right to pursue the subject matter recited by them in one or more divisional, continuation or continuation-in-part applications. Claims 20-22 and 24-28 are also canceled without prejudice. The title has been amended to more precisely reflect the subject matter of the pending claims. The pending claims are entirely supported by the specification as originally filed. No new matter has been introduced.

A. **The Rejection Under 35 U.S.C. § 102(a) Should Be Withdrawn**

On pages 3-4 of the Office Action, the claims are rejected as allegedly anticipated by U.S. Patent No. 6,391,875<sup>1</sup> to Morgan *et al.* ("the '875 patent"). In particular, it is alleged that the claims are anticipated because the '875 patent discloses a method of treating an affective disorder using (S,S)-hydroxybupropion. Office Action, page 4. However, claims 19 and 23 do not recite (S,S)-hydroxybupropion. Because a prior art reference must disclose each and every limitation of a claim in order to anticipate it, Applicants respectfully request that this rejection be withdrawn. *See, e.g., Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987).

B. **The Rejection Under 35 U.S.C. § 103(a) Should Be Withdrawn**

On pages 4-5 of the Office Action, claims 24 and 25, which correspond, in part, to pending claims 127 and 131, are rejected as allegedly obvious over the '875 patent in view of WO 99/17803 to Cary ("the '803 publication"). In particular, it is alleged that because the '875 patent discloses the use of (S,S)-hydroxybupropion for the treatment of an affective disorder, and the '803 publication discloses a method of treating nicotine addiction using an antidepressant such as bupropion, alone or in combination with nicotine transdermal patch, the claims are obvious. Office Action, page 4-5. Applicants respectfully traverse this rejection.

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<sup>1</sup> The '875 patent is an equivalent of WO 99/37305. Although WO 99/37305 was cited for the rejection, the Examiner refers to the portions of the '875 patent in the text of the rejection.

It is well-settled that three criteria must be met to establish a *prima facie* case of obviousness: 1) the prior art references must teach or suggest all the claim limitations; 2) there must be some suggestion or motivation to modify or combine the cited references; and 3) there must have been, at the time of the invention, a reasonable expectation of success. Manual of Patent Examining Procedure, § 2143.

Applicants respectfully submit that a motivation or suggestion to combine or modify the '875 patent and the '803 publication did not exist prior to this invention. For example, although it discloses a laundry list of antidepressants, the '803 publication does not disclose a bupropion metabolite. In addition, the '803 publication does not suggest that bupropion, much less a metabolite thereof, is more or less effective than any of the numerous other antidepressants it discloses when used in combination therapy.

The '875 patent does not cure this deficiency. While disclosing (S,S)-hydroxybupropion, the '875 patent is completely silent about the use of that compound in combination with any other pharmaceutically active agents whatsoever. Therefore, because neither the '803 publication nor the '875 patent specifically suggests that a bupropion metabolite be combined with another drug for the treatment of an affective disorder, those of ordinary skill in the art, would not have been motivated to try the claimed invention, and certainly would not have had any expectation of success. Consequently, Applicants respectfully request that the rejection of the claims under 35 U.S.C. § 103(a) be withdrawn.

Additional reasons exist as to why the claimed invention is not obvious over the cited references. As the Examiner recognizes, the '875 patent reports that "(S,S)-hydroxybupropion does not show the toxic effects that is associated with *other metabolites*." Office Action, page 4 (emphasis added). Therefore, by suggesting that other metabolites are toxic, the '875 patent actually teaches away from the invention recited by, for example, claims 19 and 27. *See, also*, the '875 patent, col. 8, lines 7-9. (implying that other metabolites of bupropion are unlikely to be active). For these additional reasons, Applicants respectfully request that the rejection under 35 U.S.C. § 103(a) be withdrawn.

It is further alleged in the Office Action that claim 27 is obvious over WO 99/38499 to McCullough *et al.* in view of the '875 patent. With the cancellation of claim 27, this rejection is obviated.

For the foregoing reasons, Applicants respectfully request that the rejection of the claims under 35 U.S.C. § 103(a) be withdrawn.

C. The Double Patenting Rejection Should Be Withdrawn

On pages 7-8 of the Office Action, the claims are provisionally rejected under judicially created non-statutory double patenting as allegedly unpatentable over the claims in the co-pending Application No. 09/987,930 ("the '930 application"). In light of the claim amendments made herein, and those concurrently made in the '930 application, Applicants respectfully request that the rejection be withdrawn.


Conclusion

Applicants respectfully submit that all of the pending claims are allowable, and request that rejections directed to the claims be withdrawn.

No fee is believed due for this submission. Should any additional fees be due for this submission or to avoid abandonment of the application, please charge such fees to Jones Day Deposit Account No. 503013.

Respectfully submitted,

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